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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,604	09/19/2001	Yukio Nakamura	NPR-082	6933

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KUBOVCIK & KUBOVCIK
SUITE 710
900 17TH STREET NW
WASHINGTON, DC 20006

EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,604	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is filed under 35 U.S.C. 371 on 09/19/01 having a filing date of 01/14/00 of PCT/JP00/00162. Acknowledgment is made of Applicant's claim for priority based on Japanese Application Number 11/10628, having filing date of 01/19/99. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The preliminary amendment, filed 11/20/01 and the information disclosure statement (IDS) and Form PTO-1449 filed 1/2/02 and 3/4/02, respectively are acknowledged, entered and considered. In view of Applicant's request claims 1, 2, 5 and 6 have been amended. Thus, claims 1-7 are present for examination.

OBJECTIONS TO TRADEMARKS AND THEIR USE

2. The use of trademarks or trade names "AMINOLEBAN" and "MORIHEPAMIN" have been noted in this application. The trademarks or trade names whenever they appear should be accompanied by the generic terminologies. Although, the use of trademarks or trade names are permissible in patent applications, the propriety nature of the mark should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks or trade names.

Further, the specification, which specifies the generic terminologies should include, published product information sufficient to show that the generic terminologies or the generic descriptions are inherent in the articles referred by the trademarks or

trade names. These descriptions are made because the nature and compositions of the articles denoted by trademarks or trade names can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by EPA 0 683 233.

The reference of EPA 0 683 233 discloses process for producing recombinant human albumin and an albumin formulations thereof, wherein the serum albumin comprises a plurality of amino acids containing branched amino acids and water, wherein the amino acid content of the medium or preparation may range, for example from about 0.08 to 20 w/v %, preferably from about 0.1 to 1.0 w/v % which overlaps with the ranges claimed in claims 1 and 2, and as such, reads on the limitations of claims 1-3 (See e.g., pages 2 and 5). With respect to claim 7, the reference does not disclose the intended use of albumin preparation for treatment of liver diseases; although, on page 2, lines 9-10, the reference states that HSA is a main component of plasma proteins and is used in pharmaceutical preparations for treatment of massive hemorrhage, shock, burn injury, hyperproteinemia, fetal erythroblastosis and the like. Nevertheless,

a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 1-3, and 7 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 0 683 233 taken with WO 88/01861 or Ohashi et al., (U.S. Patent No. 4,499,076).

The reference of EPA 0 683 233 discloses similarly as the instantly claimed invention a process for producing recombinant human albumin and an albumin formulations thereof, wherein the serum albumin comprises a plurality of amino acids containing branched amino acids and water, wherein the amino acid content of the medium or preparation may range, for example from about 0.08 to 20 w/v %, preferably from about 0.1 to 1.0 w/v % which overlaps with the ranges claimed in claims 1 and 2, and as such, reads on the limitations of claims 1-3 (See e.g., pages 2 and 5).

The reference of EPA 0 683 233 differs from claims 1-7 in not teaching a composition having branched amino acid which is equal to or more than 30 w/w % on the basis of a content of total amino acids and the plurality of amino acids having the composition as recited in claim 6. However, the primary reference of EPA 0 683 233 in Example I (Tables 2-4) disclosed in yield percentages but not in content ratios as claimed in claim 6. Nevertheless, Example II shows conversion of yield percentages of Histidine into concentration percentages (w/v). Based on this, it would have been obvious to one of ordinary skill in the art to convert any amino acid of interest to content ratio percentages (w/w %) as claimed in claim 6. Further, the secondary reference of

WO 88/01861 teaches the use of nutritional composition comprising a high protein source such as lactoalbumin, wherein the content of branched amino acid comprises approximately 45 to 55% w/w of the total protein and amino acid content, and as such, meets the limitations of claims 4-6 which require the content of the branched amino acids to be equal or more than 30 w/w% on the basis of a content of total amino acids. Similarly, the reference of Ohashi et al., teaches the use of elemental diets for liver diseases which contains nutritional compositions of various amino acids in molar percentages, wherein the amino acid content in the composition is 10-20 % by weight or so. Thus, the secondary reference clearly discloses mole percentages of various amino acids composition in a form of diet formulation wherein the formulation comprises an amino acid content from about 10% to 20% by weight (See e.g., col. 2 and claims 1 and 2) as directed to claims 4-6. Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would easily adjust the content ratio (w/w %) of any amino acid of interest according to the required percentages.

With respect to claim 7, the reference does not disclose the intended use of albumin preparation for treatment of liver diseases; although, on page 2, lines 9-10, the reference states that HSA is a main component of plasma proteins and is used in pharmaceutical preparations for treatment of massive hemorrhage, shock, burn injury, hyperproteinemia, fetal erythroblastosis and the like. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a

glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

Therefore, the combined teachings of the prior art makes obvious the albumin preparation containing amino acids comprising serum albumin, a plurality of amino acids containing branched amino acids and water, wherein the content of albumin is 0.01 to 1.0 w/v%, a content of plurality of amino acids containing branched amino acids is 5 to 10 w/v%, a content of the branched amino acids is equal to or more than 30 w/w% on the basis of the content of total amino acids and a Fischer ratio (molar ratio) which is equal to or more than 20, and the albumin preparation is useful for treatment of liver diseases, absence of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

AAM Mohamed/AAM

September 22, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600